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09/519,224	03/06/2000	John C. Yundi-Pacheco	HEMA.69528	7948

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Mauricio A Uribe  
SHOOK HARDY & BACON L L P  
One Kansas City Place  
1200 Main Street  
Kansas City, MO 64105-2118

EXAMINER

SUN, XIUQUIN

ART UNIT

PAPER NUMBER

2863

DATE MAILED: 02/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/519,224

Applicant(s)

YUNDT-PACHECO, JOHN C.

Examiner

Xiuqin Sun

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 19-33, 35, 36 and 39-55 is/are rejected.
- 7) ☒ Claim(s) 15, 17, 18, 34, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:

Page 7, line 9, please change "such a" into --such as a--.

Appropriate correction is required.

### ***Status of Claims***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Hence, misnumbered claims 21-54 has been renumbered as claims 22-55, respectively.

### ***Claim Objections***

3. Claims 1, 21 and 45 are objected to because of the following minor informalities:

Please change "the method comprising" into --the method comprising the steps of--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the recited laboratory information system, which is coupled to individual laboratory instruments and in communication with the normalization server, is not described or defined.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-14, 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (U.S. Pat. No. 5646046).

Fischer et al. teach a method for modifying data from a group of laboratory instruments (col. 26, lines 56-67; col. 27, lines 1-11) which comprises the steps of: obtaining data indicative of testing specimen outputs of the group of laboratory (col. 20,

Art Unit: 2863

lines 20-26); and normalizing the data according to a control group (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42).

The teaching given by Fischer et al. includes receiving the laboratory instrument outputs via a network/Internet communication link (col. 20, lines 25-26).

The teaching given by Fischer et al. includes receiving the laboratory instrument outputs via a manual input (col. 13, lines 64-67).

The normalization step taught by Fischer et al. includes obtaining control specimen data and generating a normalization curve according to the control specimen data (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42).

The Fischer method teaches the normalization curve that can be generated by applying a linear regression, and/or a nonlinear regression, and/or a spline to the group of lab instrument control specimen data and measuring the curve error for each curve (col. 21, lines 44-47; lines 57-58; and col. 22, lines 14-42).

The Fischer method further teaches returning the optimum curve with the minimized curve error as the normalization curve (col. 8, line 14; col. 22, lines 39-42).

The normalization step taught by Fischer et al. includes mapping the testing specimen group output according to the normalization curve (col. 21, lines 35-43; col. 27, lines 8-11).

The normalization curve taught by Fischer et al. is generated for a single laboratory instrument (col. 5, 57-64; col. 21, lines 32-43; col. 26, lines 66-67), thus, can be applied to each instrument in a group of laboratory instruments (col. 26, lines 60-66).

The Fischer method further teaches outputting the normalized data (col. 3, lines 58-59; and col. 21, lines 36-41);

The Fischer method further teaches a computer-readable medium having computer-executable instructions for performing the steps recited in claim 1 (col. 7, lines 59-62; col. 8, lines 14-28).

8. Claims 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (U.S. Pat. No. 5646046).

The components and the functions of the structure of the claimed system are deemed to be made clearly obvious by and/or to be inherent in the steps of the method in the combination discussed above.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 20 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (U.S. Pat. No. 5646046).

Fischer et al. teach a method for modifying data from a group of laboratory instruments (col. 26, lines 56-67; col. 27, lines 1-11) which comprises the steps of: obtaining data indicative of testing specimen outputs of the group of laboratory

Art Unit: 2863

instruments (col. 20, lines 20-26); and normalizing the data according to a control group (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42).

Fischer et al. do not mention explicitly the structure of the computer system recited in claims 20 and 55. The Examiner takes official notice that a computer system having a memory, an operating system and a central processor is well known in the art.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include such a computer system in order to execute the steps recited in claims 1 and 45.

11. Claims 21-36, 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (U.S. Pat. No. 5646046).

Fischer et al. teach a method for modifying data from a group of laboratory instruments (col. 26, lines 56-67; col. 27, lines 1-11) which comprises the steps of: obtaining data indicative of testing specimen outputs of the group of laboratory instruments (col. 20, lines 20-26); and normalizing the testing specimen outputs (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42).

Fischer et al. do not mention explicitly modifying data from more than one group of laboratory instruments.

In view of the teaching disclosed by Fischer et al. (col. 26, lines 56-67; col. 27, lines 1-11; col. 20, lines 20-26; col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42), one having ordinary skill in the art would be able to apply the same technique to carry out the method for modifying instrument results to other groups of laboratory

Art Unit: 2863

instruments. The mere application of a known method to more than one group of laboratory instruments by those skilled in the art would have been obvious.

12. Claims 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (U.S. Pat. No. 5646046).

Fischer et al. teach a method for standardizing data from a group of laboratory instruments (col. 26, lines 57-67; col. 27, lines 1-11) which comprises the steps of: obtaining data indicative of testing specimen outputs of the group of laboratory instruments (col. 20, lines 20-26); normalizing the data according to a control group (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42); and adjusting the laboratory instrument data according to the obtained normalization curve (col. 21, lines 32-43).

Fischer et al. do not mention explicitly standardizing instrument results from a plurality of laboratory instruments.

In view of the teaching disclosed by Fischer et al., one having ordinary skill in the art would be able to apply the same technique to carry out the method for standardizing instrument results to multiple groups of laboratory instruments. The mere application of a known method to more than one group of laboratory instruments by those skilled in the art would have been obvious.

### ***Allowable Subject Matter***

13. Claims 15, 17-18, 34 and 37-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 2863

14. Claim 44 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this office action.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(1) Zimmerman (U.S. Pat. No. 5941820) discloses a method for measuring data in the medical environment.

(2) Mark et al. (U.S. Pat. No. 5570304) disclose a method for modeling and updating instrument bias error which relies upon piece-wise cubic spline encoding of data.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (703)305-3467. The examiner can normally be reached from 7:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Hilten can be reached on (703)308-0719. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-5841 for regular communications and (703)308-5841 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

Application/Control Number: 09519224

Page 9

Art Unit: 2863

X.S

February 11, 2002



JOHN S. HILTEN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2800